REMARKS:

Status

Claims 1 to 23 are pending. Claims 1, 7 to 9, 11, 17 to 19, and 21 have been amended, and claims 22 and 23 have been added. Claims 1, 11, and 21 are the independent claims. Reconsideration and further examination are respectfully requested.

Section 101 Rejections

Statutory Subject Matter: Claims 1 to 20 were rejected under 35 U.S.C. § 101 as directed toward non-statutory subject matter. Claims 1 and 11 are the independent ones of these claims. Claim 1 has been amended to recite that "the step of analyzing is performed using a computing device." Claim 11 has likewise been amended to recite that "the determining steps and the merging step" (i.e., the sub-steps of the recited analyzing step) "are performed using a computing device."

The Examiner states that "[w]hen a computer-implemented method does not recite a physical step of an actual transformation of data, it may be statutory when the claimed invention as a whole accomplishes a practical application."

First, Applicant asserts that claims 1 and 11 do, in fact, recite an actual transformation of data. In particular, the claims transform genotype data into "a region in genomes of the affected people that includes markers exhibiting particular homozygous pairs of alleles more frequently than would occur randomly." This is a transformation of data.

Second, this transformation does have a practical application. In particular, identifying such a region permits sequencing of a smaller amount of DNA, resulting in significant cost savings compared to a brute-force sequencing of an entire genome. Cost savings are, of course, eminently practical. In this regard, Applicant's note that the Court of Appeals for the Federal Circuit has held that even properly determining a price (i.e., cost) is a practical application:

> Today, we hold that *the transformation of data*, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, *constitutes a practical application of a mathematical algorithm*, formula, or calculation, because it produces "a useful, concrete and tangible result"-a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades.

[Emphasis added.] State Street Bank & Trust Co. v. Signature Financial Group, Inc., 149 F.3d 1368, 1373 (Fed. Cir. 1998). This case highlights that financial considerations are relevant to determining if a transformation is practical.

Applicant has also added dependent claims 22 and 23, which recite the physical step of "sequencing the region of markers that has a highest or next-highest score."

Patentable Utility: Claims 1 to 21 were rejected under § 101 as lacking patentable utility. Applicant respectfully traverses this rejection.

In this regard, the Examiner states the following: "In order for the result of the method to be used *for determining recessive diseases in inbred population*, one skilled in the art must be aware of the correlation between the information received ... and a condition to be diagnosed" (emphasis added). However, the utility of Applicant's invention is not "for determining recessive disease in inbred populations," but rather to determine a region of a genome for more cost-

effective sequencing. Some regions will be more closely related to the genetic disease; the invention tells where to look. In this regard, the invention is similar to any scientific instrument, such as a microscope or assay, which provides test information results.

The Examiner reminds Applicant that "a 'use' *to perform further research* is not a utility under 35 U.S.C. 101." (Emphasis added.) However, the invention is *not* entirely "to perform further research"; as noted above, the invention is similar to scientific instrument, test, or assay, which tells where in the genome is a good place to look for disease markers. Thus, the invention is *not* a substance or material for which *carrying out further research to identify or reasonably confirm a 'real world' context of use* (of the invention) is required. It is unlike the "expressed sequence tags" or "ESTs" of the type discussed in *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005). Instead, Applicant's invention is a scientific or laboratory instrument, not a subject of research itself. In this regard, MPEP § 2107.01(I)(C) states the following:

> Some confusion can result when one attempts to label certain types of inventions as not being capable of having a specific and substantial utility based on the setting in which the invention is to be used. One example is inventions to be used in a research or laboratory setting. *Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility* (e.g., they are useful in analyzing compounds). An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact "useful" in a patent sense. Instead, Office personnel must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires *further research to identify or reasonably confirm*. Labels such as "research tool," "intermediate" or "for research purposes" are not helpful in determining if an applicant has identified a specific and substantial utility for the invention.

(Emphasis added). The present invention is, in fact, similar to a screening assay in that it screens for a particular region of a genome. The invention explicitly does *not* require "*further research to identify or reasonably confirm*" a real world use. It provides a real world use directly---pointing out where in the genome to look. Additional steps might be needed to determine if the region is, in fact, related to a particular genetic disease. However, this is also similar to many other screening assays or biological tests, few of which have 100% accuracy and many of which simply indicate that further screening is necessary. Clearly, limiting the field for subsequent testing is practical and useful in both cases. Just as with some screening assay, further testing (e.g., sequencing) might be needed to determine if the results of the invention were accurate in a particular instance.

The similarity to screening assays is further highlighted by MPEP § 2107.01(I)(B), which states the following:

> A "substantial utility" defines a "real world" use. Utilities that *require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use* are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. *An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring.*"

(Emphasis added). In the present case, the invention identifies a region of a genome that might be related to a genetic disease. It does not "*require or constitute carrying out further research to identify or reasonably confirm a 'real world' context of use*", as providing this information is already

a "real world" use. Thus, the invention identifies a candidate region for further monitoring (e.g., sequencing).

This section of the MPEP lists specific examples that do not define "substantial utility":

> On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":
>
> (A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;
>
> (B) A method of treating an unspecified disease or condition;
>
> (C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility;
>
> (D) A method of making a material that itself has no specific, substantial, and credible utility; and
>
> (E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.

The claimed invention is clearly distinguishable from each of these. The invention does not involve "basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved." The invention does not offer a method of treating an unspecified disease, but rather is a research tool applicable to named, specific diseases (in fact, many of them). The results of the invention have specific utility, namely identifying a region of a genome for cost-effective sequencing. The invention is not a method of making a material and is not an intermediate product for use in making another product.

In fact, the Examiner's own rejection highlights the substantial utility of the invention. As quoted above, the Examiner indicated that "[i]n order for the result of the method to be used for determining recessive diseases in inbred population, *one skilled in the art must be aware of the correlation between the information received ... and a condition to be diagnosed*" (emphasis added). Applicant respectfully disagrees. The invention indicates the possible existence of such a correlation, a fact not already known to those skilled in the art, and not only useful but often essential to further testing. Such usefulness certainly meets the standard for patentable utility.

In view of the foregoing, Applicant respectfully submits that the claimed invention meets the requirements of § 101.

Section 112 Rejections

Claims 1 to 21 were rejected for various reasons under 35 U.S.C. § 112, ¶ 2, for alleged indefiniteness. Applicant has amended the claims to address these rejections, withdrawal of which is respectfully requested.

Section 102 and 103 Rejections

All pending claims were rejected under 35 U.S.C. § 102 over Arbour et al., *Human Mol. Genet.*, 6(5):689-694 (1997) (Arbour), under § 102 over Kruglyak et al., *Am. J. Hum. Genet.*, 56:519-527 (1995) (Kruglyak), or under § 103 over Arbour in view of Kruglyak.

Applicant has amended claims 1, 11, and 21 to recite that "the set of scores that are merged for each marker include[e] at least first scores generated under a first assumption that the

marker is autozygous and second scores under a second assumption that the marker is not autozygous, the second assumption being different from the first assumption." Applicant has carefully reviewed the applied Arbour and Kruglyak references and sees no mention therein of merging these types of scores.

Arbour does mention a control population in its Abstract. Applicant notes that markers in a control are likely not to be autozygous. However, no mention is made of merging scores for a marker in this control group with scores determined under any different assumption, and definitely not an assumption that the marker is autozygous. Kruglyak likewise appears to be silent with respect to such merging.

In view of the foregoing, amended claims 1, 11, and 21 and their dependent claims are believed to be allowable over the cited art. Such action is respectfully requested.

No Admission

Applicant's decision not to argue each of the dependent claims separately is not an admission that the subject matter of those claims is taught by the applied art.

Closing

In view of the foregoing amendments and remarks, the entire application is believed to be in condition for allowance, and such action is respectfully requested at the Examiner's earliest convenience.

Applicant's undersigned attorney can be reached at (650) 947-0700. All correspondence should continue to be directed to the address indicated below.

Respectfully submitted,

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